UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,197	11/19/2003	Roald Skurtveit	NIDN-10370 CON	6244

7590 04/12/2007

Amersham Health, Inc.
101 Carnegie Center
Princeton, NJ 08540

EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,197	SKURTVEIT ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23-43 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 4/9/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23 – 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 32 of U.S. Patent No. 6,375,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to combined preparations comprising gaseous emulsions, destabilizing agents, a vasodilator and methods of use thereof, wherein the gas is a perfluorocarbon. The scope of the patented claims significantly overlaps with those of the pending claims, except that the diffusible component of the instant claims is capable of penetrating inside dispersed gas

to provide controlled growth thereof. However, it would have been obvious to one or ordinary skill in the art to practice the instantly claimed invention because all of the pending claims use diffusible components which are materially the same as those patented, thus providing similar effects as of the diffusible components of the patented claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation in claim 27 of "an initially coalescence-resisting surface membrane" renders the scope of the claim ambiguous. It is not clear what compounds are encompassed an initially coalescence-resisting surface membrane because the specification does not specify the meaning of such a limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23 – 34, 36 – 40, 42, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger (US 5,846,517) (hereinafter "Unger I").

Unger I discloses coadministration of compositions comprising gaseous liposome dispersions and a vasodilator such as enalapril (abstract; column 49, line 55; column 50, line 67; column 55, lines 1 – 30, examples 1 – 4). Unger uses various types of phospholipids including phosphopatic acid or phosphatidylglycerol (see example 1, column 61, lines 22 – 55). Unger also discloses the use of perfluorobutane (column 62, lines 40 – 41). Unger further discloses the use of stabilizers such as polyethylene glycols and emulsifying agents such as sodium lauryl sulfate (an alkyl sulfate) (column27 – 29). Regarding claims 23 – 34, 36 and 37, it is noted that Unger does not specifically recite that the role of sodium lauryl sulfate, for example, is to be a destabilizing substance to promote an increase in size of the gas; however, the instant claims are product claims and Unger teaches all of the elements of such product claims. Namely, Unger uses compositions containing polyethylene glycol and sodium lauryl sulfate (column 27 – 29). Thus, Unger anticipates the limitations of the instant product claims. With respect to claims 38 – 40, 42 and 43 Unger discloses process steps of coadministering compositions having all of the elements of the instant claims. Thus, compositions of Unger are inherently capable of growth and retention within the tissue microvasculature of interest when subject to ultrasound energy. Applicant's methodologies do not exclude the process steps of Unger (see abstract; column 49, line

55; column 50, line 67; examples 1 – 4; column 55, lines 1- 30). Therefore, Unger's methods anticipate the limitations of the instant claims.

Claims 23 – 33 and 36 – 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger (US 5,733,572) (hereinafter "Unger II").

Unger II discloses phospholipid bound gaseous contrast medium comprising a phospholipid, including phosphatidylserine, a perfluorocarbon gas in an aqueous medium comprising sodium chloride, propylene glycol and sodium dodecyl sulfate and methods of use thereof in combination with a therapeutic agent such as a radioactive particle (see example 10 and 26; column 58, lines 28 – 67; column 61, line 20; column 66, line 34). The compositions may also be used for diagnostic ultrasound (column 36).

Claims 23 – 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Ostensen *et al.* (US 6,375,931) (hereinafter "Ostensen").

Ostensen discloses preparations comprising gaseous microbubbles in combination with a vasodilator such as adenosine to enhance the signal intensity during ultrasound imaging (abstract). WO '324 discloses perfluorobutane-filled microbubbles encapsulated by phospholipid moieties such as phosphatidylserine (examples 1, 5 – 11; claims 1 – 32). The compositions may be separately packaged or may be administered separately (column 11, line 16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 – 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger II.

Unger II discloses encapsulated gaseous contrast medium comprising a phospholipid (e.g. phosphatidylserine), as set forth above. Unger does not specifically recite that adenosine is used as a vasodilator in the compositions. However, Unger cites that various cardiovascular agents such as nitroglycerin, nicardipine, or popanolol, which all cause peripheral vasodilations. In fact, Unger teaches that drugs such as adenosine can be modified in the form of prodrugs in order to assert their activities (column 25, lines 29 – 37). Unger teaches all components and method steps instantly claimed, and there is no evidence to suggest that the compositions are not capable of being administered separately. Accordingly the use of such cardiac drugs may be used in combination with Unger's compositions for their own intended clinical end point. Thus, even though Unger does not explicitly cite adenosine, rather a prodrug form thereof, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use Unger's composition with adenosine, as suggested by Unger's patent, because one would have expected to see enhanced therapeutic results using Unger's composition in combination with adenosine.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER